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**Section 5. 510(k) Summary**

JUL 11 2012

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**Date Prepared**
15 December 2011

**Trade Name**
Mongoose Angiographic Catheter

**Classification Name**
Diagnostic Intravascular Catheter

**Regulation Number**
870.1200

**Product Code**
DQO

**Classification Panel**
Cardiovascular

**Device Class**
Class II

**Predicate Devices**
1. K943739: Softouch Diagnostic Intravascular Catheter (Merit Medical is currently responsible for marketing the device originally submitted under this premarket notification).

2. K060116: Micrus Courier Microcatheters

**Indications for Use**
The Mongoose Angiographic Catheter is intended for the delivery of contrast media to selected sites in the vascular system of adult and pediatric patients of all ages in conjunction with routine diagnostic procedures.

**Device Description**
The Mongoose Angiographic Catheter is a single-use, sterile, non-pyrogenic disposable intravascular catheter for use in angiographic procedures. The Mongoose Angiographic Catheter is intended for adult and pediatric patients of all ages.

The Mongoose Angiographic Catheter is available in 3.3 F, 4.0 F and 5 F sizes. These catheters are available in effective lengths ranging from 35-135 cm and a variety of distal end shapes. The distal tip, soft tube and shaft of Mongoose Angiographic Catheters are manufactured with radiopaque barium sulfate to aid in device visualization under fluoroscopy. Catheters have a hydrophilic coating and are reinforced with wire braiding. Side holes are available to disperse the contrast medium.

An inserter is made available as an accessory to the Mongoose Angiographic Catheters with a pigtail distal configuration. The inserter facilitates insertion of the angiographic catheter into an introducer.

**Technological Characteristics and Substantial Equivalence**
The following table compares the Mongoose Angiographic Catheter to the predicate devices with respect to intended use and technological characteristics, providing more detailed information regarding the basis for the determination of substantial equivalence.

**Table 5-1. Device Comparison Table**

| Parameter | PediaCath Mongoose Angiographic Catheter | Merit Medical Performa Pediatric JL/JR and Angiography Pigtail Catheters | Micrus Courier Microcatheters |
|---|---|---|---|
| 510(k) Number | To be assigned | K943739 | K060116 |
| Indications for Use | The Mongoose Angiographic Catheter is intended for the delivery of contrast media to selected sites in the vascular system of adult and pediatric patients of all ages in conjunction with routine diagnostic procedures. | Angiographic catheters are designed to be used for delivering radiopaque media to selected sites in the vascular system in conjunction with routine diagnostic procedures. Angiographic catheters with marker bands may also be used for anatomical measurements. | The Micrus Courier microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents such as occlusion coils, into peripheral, coronary, and neuro vasculature. |
| Regulation Number | 870.1200 | 870.1200 | 870.1200 |
| FDA Product Code | DQO | DQO | DQO |
| Prescription/ OTC Use | Prescription | Prescription | Prescription |
| Single-Use/ Reusable | Single-Use | Single-Use | Single-Use |
| ***Dimensions*** | | | |
| French Sizes (available) | 3.3 F, 4 F, 5 F | 3 F, 4 F, 5 F, 6 F, 7 F | 2.3-2.4 F Proximal OD/ 1.8-1.9 F Low Profile Distal OD |
| Total Length (cm) | 42 cm – 142 cm | 40 cm – 100 cm | 156 cm |
| Recommended Guide Wire | Varies by French Size and Distal Tip Shape from 0.030" (0.76 mm) to 0.038" (0.97 mm) | Varies by catheter French Size from .021" (0.53 mm) to .038" (0.97 mm) | .014" |
| ***Physical Characteristics*** | | | |
| Lumen Construction | Single | Single | Single |
| Coating | Hydrophilic | No | Hydrophilic |

| Parameter | PediaCath Mongoose Angiographic Catheter | Merit Medical Performa Pediatric JL/JR and Angiography Pigtail Catheters | Micrus Courier Microcatheters |
|---|---|---|---|
| Reinforcement Material | Wire braid design | Wire braid design | Wire braid design |
| Distal Tip Shapes | - Pigtail<br>- JB<br>- JR<br>- JL<br>- MP<br>- Cobra | - JL<br>- JR<br>- Pigtail | - Straight<br>- 45°<br>- 90°<br>- Custom tip shape accomplished using steam-shaping mandrel supplied with catheter |
| Side Holes | Yes | Yes | No |
| ***Sterilization and Shelf Life*** | | | |
| Sterilization Method | Ethylene oxide | Ethylene oxide | Ethylene oxide |
| Non-Pyrogenic | Yes | Yes | Yes |
| Sterile Package | Pouch | Pouch | Pouch |
| Shelf Life (Use By Date) | Three (3) years | Three (3) years (at minimum) | One (1) year |

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**Summary of Non-Clinical Data Submitted**

Performance testing was conducted on the Mongoose Angiographic Catheter to establish substantial equivalence. Testing was conducted according to protocols based on international standards and in-house requirements, and included dimensional and functional testing. Functional performance testing included surface requirements, corrosion resistance, tensile strength, leakage tests, radiodetectability and tests specific to catheter fittings. The Angiographic Catheter was subjected to biocompatibility testing in accordance with ISO 10993-1:2009. Additionally the Mongoose Angiographic Catheter was adopted into the existing ethylene oxide sterilization cycle which was validated in accordance with ISO 11135-1:2007.

**Safety and Effectiveness**

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics, and it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Mongoose Angiographic Catheter and predicate devices do not raise any questions regarding its safety and effectiveness. The Mongoose Angiographic Catheter, as designed and manufactured, therefore is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Pediacath Inc.
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JUL 11 2012

Re: K113819
Trade/Device Name: Mongoose Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: June 21, 2012
Received: June 22, 2012

Dear Mr. Moran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K113819

Device Name: Mongoose Angiographic Catheter

Indications for Use: The Mongoose Angiographic Catheter is intended for the delivery of contrast media to selected sites in the vascular system of adult and pediatric patients of all ages in conjunction with routine diagnostic procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113819